#### AN OSTOMY APPLIANCE

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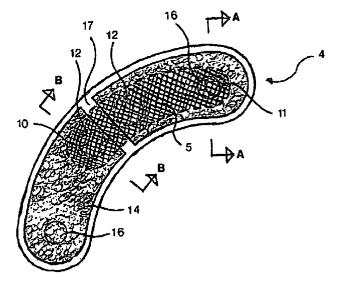
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#### Abstract of WO03020188

An ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, the rear wall having an opening into the bag by which waste material can enter the bag and one of the walls has one or more vents through which gas may escape from the bag and having a filter covering said vent wherein gas inlet and outlet openings and provided in communication with a filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flo w being confined to said filter body, wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having separated inlet openings communicating with the bag and separate and independent outlet openings communicating with the inlet opening of the filter, and wherein each of the outlet openings of the separate pathways are covered by a microporous membrane shows improved resistance against blocking of the inlet opening of filter.



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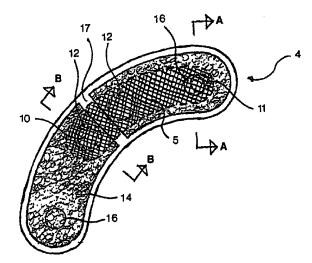
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#### (54) Title: AN OSTOMY APPLIANCE



(57) Abstract: An ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, the rear wall having an opening into the bag by which waste material can enter the bag and one of the walls has one or more vents through which gas may escape from the bag and having a filter covering said vent wherein gas inlet and outlet openings and provided in communication with a filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flo w being confined to said filter body, wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having separated inlet openings communicating with the bag and separate and independent outlet openings communicating with the inlet opening of the filter, and wherein each of the outlet openings of the separate pathways are covered by a microporous membrane shows improved resistance against blocking of the inlet opening of filter.

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#### TITLE

An Ostomy Appliance

#### **BACKGROUND OF THE INVENTION**

#### 1. Field of the Invention

5 The present invention relates to an ostomy appliance comprising a deodorising filter, in particular ostomy bags, and to a filter device.

In connection with surgery for a number of diseases in the gastro-intestinal tract a consequence is, in many cases, that the patient is left with a stoma such as a colostomy, an ileostomy or an urostomy in the abdominal wall for the discharge of the effluents or waste products of the body, which are conveyed through the colon, the ileum or the ureter. The discharge of visceral contents including intestinal gases cannot be regulated at will, and for that purpose the opening may be closed with a closure means, e.g. a tampon or a magnetic closure, or the patient will have to rely on an appliance to collect the material emerging from such opening in the form of a receiving bag which is later emptied and/or discarded at suitable times.

Ostomy appliances are well known. Such appliances may be two-piece or one-piece appliances. In both types of appliances, an adhesive wafer is attached to the wearer's skin. In case of a one-piece appliance, a receiving member or bag is attached to the adhesive wafer. In case of a two-piece appliance, the adhesive wafer forms part of a body side member and a receiving bag is attached releasably to the body side ostomy member for receiving exudates from the stoma.

When using one-piece appliances, the whole appliance, including the adhesive skin barrier securing the appliance to the skin is normally removed and replaced by a fresh appliance. When using two-piece appliances, the body side member is left in place up to several days, and only the receiving bag attached to the body side member is replaced.

The discharge of flatus, measured in volume, may exceed the discharge of solid and liquid faecal matter by many hundred percent and therefore there is usually the need for the continuous or frequent venting of the intestine or the collecting bag. Normally the outflowing flatus is deodorised with a suitable filter. Commonly the active filter is powdered active carbon, which absorbs H<sub>2</sub>S being the principal component of the smell of flatus.

#### 2. Description of the Related Art

Various constructions of filters for ostorny appliances are known. In the state of the art, the filters are designed so as to obtain a high security of deodorisation of the flatus by securing that there is no by-pass by which the flatus may circumvent the filter, and some measures have been discussed with respect to obtaining a better security against blocking of the inlet of the filter by solid discharged visceral content. When the inlet opening of the filter is blocked, the gas discharged into the ostorny appliance cause ballooning of the bag which is highly undesirable for several reasons. Ballooning will be embarrassing for the user as the bag will bulge and there is an increased risk of leakage which is unacceptable for the user.

European Patent No. 0 235 928 discloses that a filter may be rendered suitable for use with ileostomy equipment when the filter wall adapted to face the source of intestinal gas is covered by a layer of sheet material, preferably plastic sheet material connected to the filter walls and inside the periphery of this connection, provided with openings for the passage of intestinal gas. Conveniently these openings, which may for instance be slits of a width of 0.5 - 1 mm and a length of a few millimetres, may be situated outside the peripheral edge of the filter body.

However, such slits may open if the pressure is high giving free flow of gas and liquid through the layer of sheet material. In the alternative, it is proposed to provide the filter housing on the surface adapted to face the source of intestinal gas with a layer of liquid-absorbing material. The area of the absorbent material is conveniently the same as the area of the filter body or somewhat larger but the positioning on the wall in question should be such that the absorbent material does not cover the inlet opening for intestinal gas to be deodorised since saturation of the liquid-absorbing material with liquid might prevent the passage of the

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intestinal gas. Furthermore, it is proposed to render the filter particularly efficient for ileostomy equipment by providing it both with a covering sheet and an absorbent layer of material.

EP patent No. 0 443 728 B1 discloses a bag for receiving discharge from the human body comprising a filter and an intervening membrane covering the inlet opening of the filter, said intervening membrane being gas permeable but not liquid permeable. It is mentioned that the membrane may comprise a polyester film bonded to a PTFE film and that such membrane showed no leakage of water. There is no indication of security against leaking when exposed for discharge from an ileostomy or liquids from a colostomy.

US patent No. 5,342,434 discloses a gas permeable coated porous membrane having enhanced oleophobic and hydrophobic properties. The membrane may be a PTFE membrane coated with a diisocyanate coating and the membranes are stated to be useful in waterproof, breathable fabrics and gas vents or filters that protect electronic equipment used in or near automotive engines. Although other useful applications are stated to be medical devices where venting filters are needed, this reference is silent with respect to safety against wetting of filters for ostomy appliances by the visceral contents of an ostomy collection bag which contents has a very complex composition of biologically active compounds from the digestive system.

US Patent No. 4,387,712 discloses a surgical collection bag having two opposed walls secured together by a perimeter weld, said bag having a vent and said bag also having welds inside the bag defining together with the perimeter weld a pathway through which gases can flow from the interior of the bag to the vent.

The pathway includes one or more vents through which gases must pass before reaching the vent.

Published International Patent Application WO 98/44880 discloses a filter for covering a vent of an ostomy appliance, said filter comprising an elongated, substantially flat filter body of a porous filter material interposed between gas and liquid impervious walls which are sealed to the body along its longitudinal side

edges; gas inlet and outlet openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, wherein the inlet opening is covered by a hydrophobic sheet,

5 wherein the inlet opening is covered with a microporous oleophobic membrane and wherein a foam material is covering the inlet opening of the vent. It is disclosed that there may a compartment functioning as an inlet pathway, which pathway may have one or more openings for letting in gas from the interior of the ostomy appliance. Such arrangement shows improved resistance against wetting and blocking of the filter caused by humidity or other liquid constituents of the visceral contents of an ostomy collection bag and, at the same time, shows improved resistance against clogging of the filter.

However, it has been found that, especially for ostomates having an ileostomy and especially at night when they turn in bed, there is a risk of directly pressing faeces in the receiving bag against the inlet opening(s) of the filter and that the pressure may be sufficiently high to force the front of visceral material through a foam material covering a single inlet opening of the vent and past the inlet opening of the filter to cause a blocking of a microporous oleophobic membrane covering the inlet opening of the vent as the one or all of the passage way(s) communicate with one and the same compartment. This applies to both US Patent No. 4,387,712 and Published International Patent Application WO 98/44880 which both discloses only one inlet opening to the filter.

Thus, there is still a need of measures for effectively preventing blocking of the inlet opening of filters of ostorny appliances.

25 It has now been found that it is possible to reduce the risk of blocking of the inlet opening of filters of ostomy appliances in a manner that almost eliminates the risk and, at the same time, is simple to carry out in industrial practice.

Thus, it has been found that the above drawbacks can be avoided by improving the form of the passage to the inlet opening of the filter.

#### SUMMARY OF THE INVENTION

The invention relates in a first aspect to an ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, the rear wall having an opening into the bag by which waste material can enter the bag and one of the walls has one or more vents through which gas may escape from the bag and having a filter covering said vent wherein gas inlet and outlet openings are provided in communication with a filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body.

The invention furthermore relates to a deodorising filter device especially apt for covering a vent of an ostomy appliance or the like, which filter comprises a filter body of a porous filter material interposed between gas and liquid impervious walls which are sealed to the body along its edges; gas inlet and outlet openings being provided in communication with the filter material, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having separated inlet openings communicating with the bag and outlet openings communicating with the inlet opening of the filter.

#### **Brief Description of the Drawings**

The invention is disclosed more in detail with reference to the drawings in which

- Fig. 1 shows an embodiment of an ostomy appliance of the invention,
- 25 Fig. 2 shows another embodiment of an ostomy appliance of the invention,
  - Fig. 3 shows a further embodiment of an ostomy appliance of the invention
  - Fig. 4 shows an embodiment a filter device of the invention,
  - Fig. 5 shows a section along the line A-A of the embodiment of Fig 4,
  - Fig. 6 shows a section along the line B-B of the embodiment of Fig 4
- 30 Fig. 7 shows schematically the embodiment of Fig. 4 seen from the inlet side, and

Fig. 8 shows an exploded sectional view of the embodiment of Fig. 7.

#### **Detailed Description of the Present Invention**

The present invention relates to an ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, the rear wall having an opening into the bag by which waste material can enter the bag and one of the walls has one or more vents through which gas may escape from the bag and having a filter covering said vent wherein gas inlet and outlet openings are provided in communication with a filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body, wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having separated inlet openings communicating with the bag and separate and independent outlet openings communicating with the inlet opening of the filter and wherein each of the outlet openings of the separate pathways are covered by a microporous membrane.

In an alternative embodiment, the filter has more than one inlet opening in which case microporous membranes may cover these openings instead.

The risk of blocking of the inlet opening of the filter is significantly reduced by the presence of separate and independent closed pathways having separated inlet openings communicating with the interior of the bag and separate outlet openings communicating with the inlet opening of the filter, wherein each of the outlet openings of the separate pathways are covered by a microporous membrane. Thus, material present in a bag of the invention is prevented from entering through one entrance and past the inlet opening of the filter to cause a blocking of other entrances. Furthermore, the presence of separated inlet openings also reduces the probability of material present in the bag entering, at the same time, both pathways leading to the inlet opening of the filter which has been found nearly to eliminate the risk of blocking of the filter by directly pressing the contents of the bag against the inlet opening(s) of the filter e.g. when a lying person turns. e.g. in bed.

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The effect of having at least two independent closed pathways having separated inlet openings is improved when the separated inlet openings are spaced a certain distance from each other, a certain effect being found already at a distance of at least 15 mm, the effect increasing with increasing distance until a distance comparable to the width of the bag is reached. It is preferred, that the distance is at least 50 mm and it is especially preferred, that the distance corresponds to 90% of the width of the bag for which the filter device is intended.

It provides a pronounced effect when the pathways stretch essentially along radii of a circle of reference having a perimeter concentric with the inlet opening of the filter and that the inlet openings of the pathways are spaced at an angle of at least 45 degrees, and it is preferred that the inlet openings are spaced at an angle of at least 90 degrees which ensures that a pressure along one passage will act perpendicular to the other.

It is especially preferred that the inlet openings are spaced at an angle of at

15 least 135 degrees which will be very suitable taking into account the shape of a
bag where the filter device is to be placed but angles of up to 180 degrees are
considered suitable for the purpose of the present invention.

In a preferred embodiment the invention relates to an ostomy appliance comprising a filter comprising an elongated, substantially flat filter body of a porous filter material and wherein the gas inlet and outlet openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, the arrangement being so that in use gas flows longitudinally through the filter from the inlet opening to the outlet opening, wherein the gas inlet opening to the filter is provided with at least two independent closed pathways having separate inlet openings communicating with the bag and outlet openings communicating with the inlet opening of the filter.

The ostomy receiving bag according to the invention may be adapted for use together with an ostomy body side member (2-piece appliance) wherein the receiving bag is provided with coupling means for releasable securing to matching coupling means placed on the ostomy body side member and wherein the

inlet opening is adapted for alignment with a hole of the ostomy body side member for receiving a stoma.

The ostomy receiving bag according to the invention may, as an alternative, be adapted for use directly (1-piece appliance) in which case the bag is provided with an adhesive wafer for securing the receiving bag to the user's skin, said bag and wafer having an inlet opening for receiving a stoma.

The receiving bag itself comprising front and rear walls sealed together along the rim and provided with an inlet opening may be made in analogy with and from materials conventionally used for the preparation of ostomy appliances.

Such materials are suitably films composed of any suitable material which is heat sealable and sufficiently impervious for unpleasant odours such as polyolefin films or combinations of such films, e.g. polyethylene or a coextrudate of polyethylene and polyvinylidene chloride (PVDC).

An ostomy body side member for use together with an ostomy receiving bag
according to the invention may be produced from standard materials normally
used for preparation of disposable ostomy and wound and incontinence devices.

Thus, the adhesive wafer for a body side member or of a 1-piece ostomy appliance bag according to the invention may be made from a medical grade barrier adhesives known in the such as the formulation being disclosed, for example in US Patents Nos. 4,367,732, 5,051,259 or 5,714,225. For a 2-piece ostomy appliance according to the invention the body side member and the receiving bag are provided with matching coupling means.

The coupling means for use in connection with the present invention may be any suitable coupling means known per se for coupling of ostomy base plates to ostomy collecting bags, e.g. a mechanical coupling such as matching coupling rings such as the coupling rings disclosed in WO 91/01118 and WO 91/01119 or WO 94/18919 or matching flanges for adhesive connection of the type disclosed in U.S. Patent No. 5,800,415.

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In a further aspect, the invention relates to a deodorising filter device especially apt for covering a vent of an ostomy appliance or the like, which filter comprises a filter body of a porous filter material interposed between gas and liquid impervious walls which are sealed to the body along its edges; gas inlet and outlet openings being provided in communication with the filter material, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having separated inlet openings communicating with the bag and separate and independent outlet openings communicating with the inlet opening of the filter and wherein each of the outlet openings of the separate pathways are covered by a microporous membrane.

In a preferred embodiment, the invention relates to a deodorising filter device

15 especially apt for covering a vent of an ostomy appliance or the like, which filter comprises an elongated, substantially flat filter body of a porous filter material interposed between gas and liquid impervious walls which are sealed to the body along its edges, gas inlet and outlet openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, the arrangement being so that in use gas flows longitudinally through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body wherein the gas inlet opening to the filter is provided with at least two independent closed pathways having separated inlet openings communicating with the bag and outlet openings communicating with the inlet opening of the filter. Such filter device is very suitable for use in an ostomy appliance.

The independent closed pathways may suitably be formed using one or more further wall(s) made from a sheet material such as foils, woven or non-woven sheet materials which are moisture resistant and may be sealed to the liquid impervious wall comprising the inlet opening of the filter by welding in a corresponding pattern which is readily determined by the skilled in the art.

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It is preferred that the inlet of the filter from each pathway is protected by a microporous hydrophobic membrane and that the membrane is covered with a wall defining a space for placing a piece of a foam material, said wall being sealed to the filter with a welding seam crossing the membrane, thereby defining the outlet openings of the two independent closed pathways.

It is preferred that the closed pathways are in the form of elongated canals providing a relatively long distance form the inlet of the pathway to the outlet of the pathway and the inlet of the filter as a very high security is obtained that the material shall not reach the outlet of the canal and block the membrane physically.

In a more preferred embodiment, two separated pieces of foam are placed between two walls of sheet material separated by a welding seam, the outlets of the two independent closed pathways each having a microporous hydrophobic membrane covering the outlet opening of the canal.

15 In this embodiment, the welding pattern assembling the filter and the pathways are preferably shaped in a manner ensuring that each of the pathways, via the membranes, are communicating with the inlet opening of the filter through a common closed collecting space. This embodiment enables the use of a conventional filter package as a part of a filter device or an ostomy appliance of the invention.

The effect of having at least two independent closed pathways having separated inlet openings is improved when the separated inlet openings are spaced a certain distance from each other, a certain effect being found already at a distance of at least 15 mm, the effect increasing with increasing distance until a distance comparable to the width of the bag for which the filter device is intended is reached. It is preferred, that the distance is at least 50 mm.

For the reasons stated above it is suitable when the pathways stretch along radii of a circle having a perimeter concentric with the inlet opening and that the inlet openings are spaced at an angle of at least 45 degrees, and it is preferred that

the inlet openings are spaced at an angle of at least 90 degrees, more preferably at an angle of at least 135 degrees but angles of up to 180 degrees are considered suitable for the purpose of the present invention.

In a further preferred embodiment of a filter device of the invention the

membranes covering the outlet openings of the canals comprise a layer of a
non-woven material and a layer of an oleophobic PTFE-material which further
reduces the risk of wetting of the filter material due to the special composition
and aggressiveness of the visceral contents.

It is especially preferred that a foam material is present in the pathways as the foam material further improves the security against blocking of the inlet opening to the filter.

The rejection capacity of the foam material is enhanced when it is rendered hydrophobic which is considered a preferred embodiment.

The foam material is suitably rendered hydrophobic by treatment with a silicone oil being inert to visceral contents.

The foam material is preferably also rendered oleophobic in order to further improve the security against material reaching and blocking of the inlet opening to the filter.

It is preferred that the filter body has a curved shape facilitating the placing 20 inside an ostomy bag.

It is especially advantageous that the top of the filter device and the bag to which it is to be attached have essentially circular shape as this allows for an essentially free placing of the filter at the most appropriate site in the top of the bag.

The walls of the filter device are preferably of a size leaving an outer rim or

25 flange being apt for securing the filter device to an ostomy appliance. The device
may be secured and sealed by any suitable means, e.g. by welding or gluing.

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The filter device may be secured to a wall of an ostomy appliance at any suitable step in a conventional process for preparing ostomy appliances and it is within the scope of the invention to produce the inlet hole after securing the filter device, e.g. by cutting or punching a hole through the wall of the appliance and the filter device, this instance referring to the situation when placed inside the bag. If the filter is placed outside the bag, two holes for the inlets of the two separated pathways would have to be cut.

The front sheet and the backing sheet may be of any suitable material, preferably a material normally used for the preparation of ostomy appliances or a

10 material which may be glued or welded to such materials, e.g. PE, EVA,
polyvinylidene chloride, and chlorinated polyethylene or copolymers of PE and
EVA or combinations of such foils.

Suitable materials for use as walls for forming the independent closed pathways are sheet materials such as foils, or porous woven or non-woven sheet materials which are moisture resistant and may be united with materials conventionally used in the production of ostomy appliances such as non-woven materials of polyethylene, polypropylene or a polyester.

The filter body may be formed in various ways and may advantageously consist of a compressed foamed plastic impregnated with (i.e. containing in its pores) a highly activated carbon as disclosed in WO 98/44880.

Foam materials suitable for use in the pathways according to the invention are open cell foam materials being resistant to the aggressive environment in of the visceral contents discharge from the ostomy and not giving rise to liberation of noxious materials. An example of a suitable material is an open-cell polyether foam or an open-cell polyurethane foam, preferably having a thickness of from 0.5 to 10 mm, more preferred from 1 to 5 mm.

#### **Description of the Preferred Embodiments**

The invention is now explained more in detail with reference to the drawings showing preferred embodiments of the invention.

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Reference is made to Fig. 1, seen from the side facing the user, which shows a preferred one-piece embodiment of an ostomy appliance of the invention comprising a front wall and a rear wall of a flexible material, said rear wall having an opening 1 into the bag by which waste material can enter the bag and. The 5 appliance has an adhesive wafer 2 for adhering to the user's skin. Furthermore, the appliance has a vent opening 3 on the front wall through which gas may escape from the bag, said vent opening being covered of a filter device 4 according to the invention wherein gas inlet and outlet openings are provided in communication with the filter body, the arrangement being so that in use, gas 10 flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body, wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having inlet openings communicating with the bag and outlet openings communicating with the inlet opening of the filter and wherein the inlet opening of the filter is 15 protected by a microporous hydrophobic and oleophobic membrane covered with a protecting layer in the form of a foam material. The filter device is preferably secured to the wall by welding in a manner known per se.

The hydrophobic and oleophobic membrane reduces the risk of wetting of the filter material and the foam material improves the security against blocking of the inlet opening to the filter. This effect is further enhanced by the independent closed pathways having inlet openings communicating with the interior of the bag and outlet openings communicating with the inlet opening of the filter. Thus, material present in the bag is hampered from entering, at the same time, both pathways leading to the inlet opening of the filter which has been found nearly to eliminate the risk of blocking of the filter by directly pressing the contents of the bag against the inlet opening(s) of the filter e.g. when a lying person turns. e.g. in bed.

Fig. 2 shows another embodiment of an ostomy appliance of the invention corresponding to the embodiment of Fig. 1 apart from the placing of the filter device 4 which in this case is placed offset from the vertical centre line of the bag,

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Fig. 3 shows further embodiment of an ostomy appliance of the invention in the form of an open ostomy appliance which, apart from the filter device **4**, corresponds to the collecting bag disclosed in WO 99/66859.

As it will further appear from the embodiments shown in Figures 1 - 3, the essentially circular shape of the top of the bag and the filter device allows for an essentially free placing of the filter at the most appropriate site place in the top of the bag.

Reference is now made to Fig. 4 which shows a preferred embodiment of a filter device 4 according to the invention comprising an elongated, substantially flat 10 filter body 5 of a porous filter material interposed between gas and liquid impervious walls 6,7 as appears from Figs. 5 and 6 which are sealed to the body along its side edges 8,9 as appears from Figs. 5 and 6; gas inlet 10 and outlet 11 openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, wherein both of the gas and liquid impervi-15 ous walls are sealed to the upper and lower surfaces of the filter body, the arrangement being so that in use gas flows longitudinally through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body and wherein the inlet opening is protected by hydrophobic sheets 12 covering the outlet openings of the closed pathways 18,19 which sheets are micropor-20 ous oleophobic membranes. The microporous oleophobic membranes are covered with a wall 13 defining a space for placing a foam material 14 to avoid physical blocking which wall is secured to the wall 6 of the filter or to a layer 15 of the ostomy appliance. The wall 13 may be made from a suitable plastic material such as a polyolefin, e.g. PE, and may be secured above and below the inlet of 25 the filter letting the sides open or may be secured around the opening and have inlet openings 16 allowing gas to enter from the ostomy appliance.

The layer 15 offers a simplification during the production of the filter device as the membrane 12 may be secured to the layer 15 before the final assembling of the filter. The layer 15 may stretch beyond the limits of the filter and be secured directly to the wall of the ostomy appliance. The wall 15 is sealed to the wall 6

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defining a space 20 for collecting the gas passing through the membranes 12 and leading the gas to the inlet opening 10.

Furthermore, there is a sealing 17 sealing the walls 13 and 15 together between the two membranes 12 separating the two independent closed pathways 18 and 19 Thus, the gas may flow from the bag through one of the inlet openings 16 through the foam material and the membranes 12 into the space 19 ensuring that all gas passes through the full length of the filter body 5, irrespective of which pathway is used.

Details with respect to the inlet and outlet openings of the various parts of the filter device of this embodiment appear from the sectional views along the lines A-A and B-B shown in Fig. 5 and Fig. 6, respectively.

Reference is made to Figs. 7 and 8 showing the principle of the embodiment shown in Fig. 4 in the form of a filter device 4 for an ostomy appliance or the like, the filter device comprising an elongated, substantially flat filter body 5 of a 15 porous filter material interposed between gas and liquid impervious walls 6,7 which are sealed to the body along its side edges 8,9; gas inlet 10 and outlet 11 openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, the 20 arrangement being so that in use gas flows longitudinally through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body and wherein the inlet openings are covered by a hydrophobic sheets 12 which sheets are microporous oleophobic membranes. The microporous oleophobic membranes are covered with a wall 13 defining a space for placing a 25 foam material 14 to avoid physical blocking which wall is secured to the wall 6 of the filter or to a layer 15 of the ostomy appliance. The wall 13 may be made from a suitable plastic material such as a polyolefin, e.g. PE, and may be secured above and below the inlet of the filter letting the sides open or may be secured around the opening and have inlet openings 16 allowing gas to enter from the 30 ostomy appliance.

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The layer 15 offers a simplification during the production of the filter device as the membrane 12 may be secured to the layer 15 before the final assembling of the filter. The layer 15 may stretch beyond the limits of the filter and be secured directly to the wall of the ostomy appliance. The wall 15 is sealed to the wall 6 defining a space 20 for collecting the gas passing through the membranes 12 and leading the gas to the inlet opening 10. This embodiment enables the use of filter packages having only one inlet opening to the filter body enhancing the efficiency of the filter material.

Furthermore, there is a sealing 17 sealing the walls 13 and 15 together between the two membranes 12 separating the two independent closed pathways 18 and 19 Thus, the gas may stream from the bag through one of the inlet openings 15 through the foam material and the membranes 12 into the space 19 ensuring that all gas passes through the full length of the filter body 5, irrespective of which pathway is used.

# 15 MATERIALS AND METHODS EXAMPLE

Preparation of a filter part of a filter device according to the invention.

A coal package consisting of a filter body of foam impregnated with coal and having a width of 7 mm, a length of 40 mm and a thickness of 2 mm, sealed between two barrier foils comprising the layers EVA, PVDC, EVA and CPE (chlorinated ployethylene), was produced by heat welding the layers around the filter body.

Two hydrophobic and oleophobic membranes were welded over preformed holes placed close to each other in a laminated barrier sheet consisting of EVA, PVDC,

25 EVA and CPE. To the other side of the sheet, the coal package was welded having an inlet hole aligned with one of the membranes only. This entity is defined as the coal/membrane package.

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Two pieces of polyether foam with a width of 8 mm, a length of 33 mm and a thickness of 1 mm were placed on a piece of non-woven fabric leaving an area in between free. The non-woven layer was heat welded to the filter package enclosing the foam pieces in two separate compartments each communicating with one of the hydrophobic and oleophobic membranes between the non-woven layer and the coal package. This product is referred to as a "filter package".

The rim of the finished filter package was trimmed into the desired final shape.

The filter may be used together with any ostomy appliance and may be placed on the wall inside or outside the ostomy appliance, on the front side or the back side of the appliance as it is found suitable for the application in question and is suitably heat welded to the wall of a bag.

#### **Claims**

- An ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, the rear wall having an opening into the bag by which waste material can enter the bag and one of the walls has one or more vents
   through which gas may escape from the bag and having a filter covering said vent wherein gas inlet and outlet openings are provided in communication with a filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body, wherein the gas inlet opening to the filter is provided with at least two
   separate and independent closed pathways having separated inlet openings communicating with the bag and separate and independent outlet openings communicating with the inlet opening of the filter and wherein each of the outlet openings of the separate pathways are covered by a microporous membrane.
- An ostomy appliance as claimed in claim 1, characterised in that the
   pathways stretch essentially along radii of a circle of reference having a perimeter concentric with the inlet opening of the filter and that the inlet openings of the pathways are spaced at an angle of at least 45 degrees.
- An ostomy appliance as claimed in claim 1 or 2 comprising a filter comprising an elongated, substantially flat filter body of a porous filter material and wherein the gas inlet and outlet openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, the arrangement being so that in use gas flows longitudinally through the filter from the inlet opening to the outlet opening, wherein the gas inlet opening to the filter is provided with at least two independent closed pathways having separated inlet openings communicating with the bag and outlet openings communicating with the inlet opening of the filter.
  - 4. A deodorising filter device especially apt for covering a vent of an ostomy appliance or the like, which filter comprises a filter body 5 of a porous filter material interposed between gas and liquid impervious walls 6,7 which are

sealed to the body along its edges **8,9**; gas inlet **10** and outlet **11** openings being provided in communication with the filter material, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, the arrangement being so that in use gas flows through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body wherein the gas inlet opening to the filter is provided with at least two separate and independent closed pathways having separated inlet openings communicating with the bag and separate and independent outlet openings communicating with the inlet opening of the filter, and wherein each of the outlet openings of the separate pathways are covered by a microporous membrane.

- 5. A filter as claimed in claim 4, which filter comprises an elongated, substantially flat filter body 5 of a porous filter material interposed between gas and liquid impervious walls 6,7 which are sealed to the body along its edges 8,9; gas inlet 10 and outlet 11 openings being provided in communication with the filter material adjacent to its respective longitudinal end regions, wherein both of the gas and liquid impervious walls are sealed to the upper and lower surfaces of the filter body, the arrangement being so that in use gas flows longitudinally through the filter from the inlet opening to the outlet opening, such gas flow being confined to said filter body wherein the gas inlet opening to the filter is provided with at least two independent closed pathways having separated inlet openings communicating with the bag and outlet openings communicating with the inlet opening of the filter.
- A filter device as claimed in claim 4 or 5, characterised in that the inlet openings are covered by microporous hydrophobic membranes 12 and the
   microporous hydrophobic membranes are covered with a wall 13 defining a space for placing a foam material 14 covering the inlet opening of the vent and that there is a sealing 17 sealing the walls 13 and 15 together between the two membranes 12 separating two independent closed pathways 18 and 19.
- A filter device as claimed in any of claims 4-6, characterised in that the
   pathways stretch essentially along radii of a circle of reference having a

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perimeter concentric with the inlet opening of the filter and that the inlet openings of the pathways are spaced at an angle of at least 45 degrees.

- 8. A filter device as claimed in any of claims 6 or 7, characterised in that the membranes 12 covering the inlet openings comprise a layer of a non-woven
  5 material and a layer of an oleophobic PTFE-material.
  - 9. A filter device as claimed in any of claims 4-8, characterised in that a foam material is present in the pathways 18 and 19.
  - 10. A filter device as claimed in claim any of claims 5-9, characterised in that the filter body has a curved shape.

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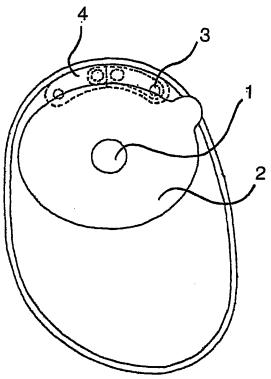


Fig. 1

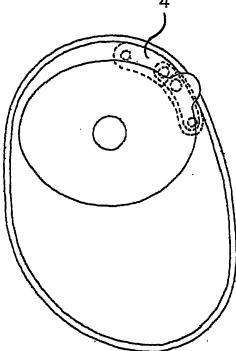


Fig. 2

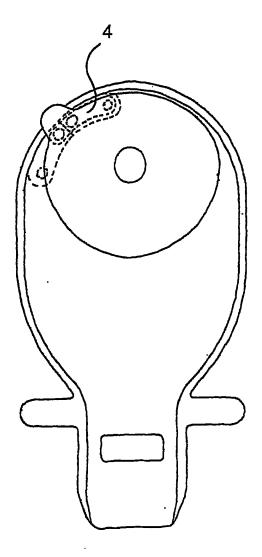


Fig. 3

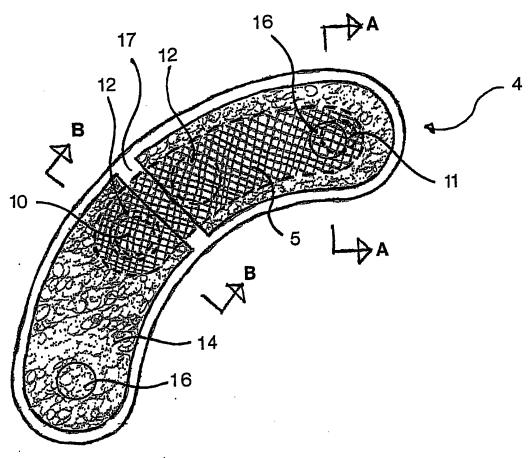
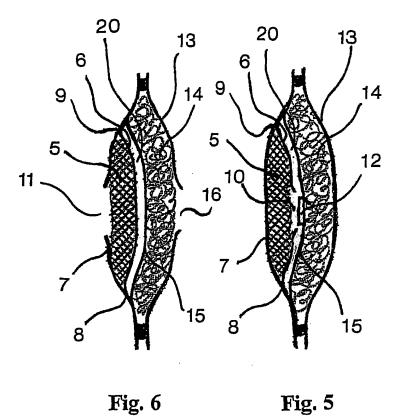


Fig. 4

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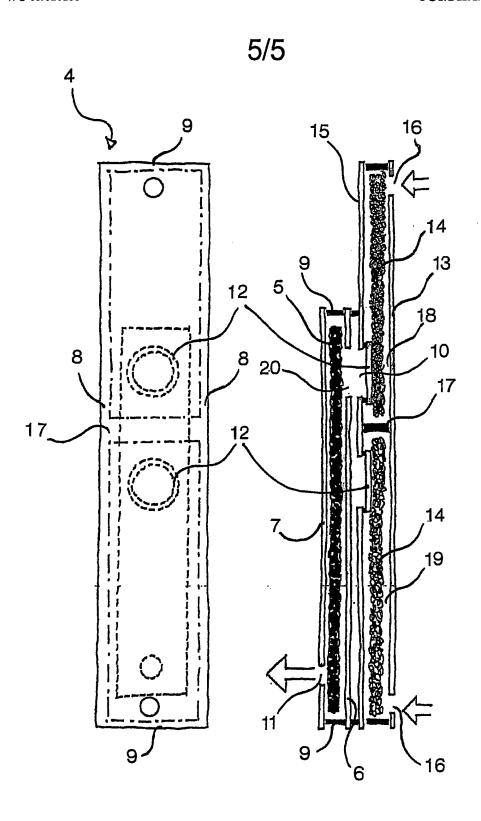


Fig. 7

Fig. 8

## IN RNATIONAL SEARCH REPORT

Intelligional Application No PCT/DK 02/00577

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F5/441										
According to International Patent Classification (IPC) or to both national classification and IPC										
B. FIELDS SEARCHED										
Minimum documentation searched (classification system followed by classification symbols)  IPC 7 A61F										
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched										
Etectronic d	ata base consulted during the international search (name of data bas	se and, where practical,	search terms used	)						
EPO-Internal										
C. DOCUMENTS CONSIDERED TO BE RELEVANT										
Category °	Citation of document, with indication, where appropriate, of the rela	Relevant to daim No.								
X	US 4 387 712 A (BRIGGS PETER J E 14 June 1983 (1983-06-14) cited in the application	1-3								
γ	column 2, line 8 - line 55; figur	4–10								
Y	WO 98 44880 A (COLOPLAST AS ;LEISNER HENRIK (DK); OLSEN ESKIL HOIJLAND (DK)) 15 October 1998 (1998–10–15) cited in the application the whole document			4–10						
А	GB 2 083 760 A (DOWNS SURGICAL LT 31 March 1982 (1982-03-31) abstract; figures	D)		1						
Further documents are listed in the continuation of box C. X Palent family members are listed in annex.										
* Special categories of cited documents : "T" later document published after the international filing date										
*A' document defining the general state of the art which is not considered to be of particular relevance or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  *E' earlier document but published on or after the International 'X' document of particular relevance; the claimed invention										
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### INTERNATIONAL SEARCH REPORT

Information on patent family members

Intermional Application No
PCT/DK 02/00577

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 4387712	A	14-06-1983	CA	1144839 A1	19-04-1983
			DE	2928274 A1	07-02-1980
			DK	300879 A	20-01-1980
			FR	2431285 A1	15-02-1980
			GB	2031282 A ,B	23-04-1980
			ΙT	1117407 B	17-02-1986
			JP	55021989 A	16-02-1980
WO 9844880	A	15-10-1998	AU	742004 B2	13-12-2001
			AU	6918798 A	30-10-1998
			BR	9809081 A	01-08-2000
			CN	1251980 T	03-05-2000
			WO	9844880 A1	15-10-1998
•			EP	0981311 A1	01-03-2000
			JP	2001519696 T	23-10-2001
			NO	994883 A	08-12-1999
			US	6135986 A	24-10-2000
			EP	0888760 A1	07-01-1999
GB 2083760	A	31-03-1982	US	4449970 A	22-05-1984